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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,782	07/21/2005	Zehra Rowjee	30479/39572A	5741

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,782	ROWJEE, ZEHRA	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as acyclovir and valacyclovir which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 1-20 are directed to encompass nucleoside analog prodrugs, acyclovir prodrugs, analogs of valacyclovir, nucleoside analogs and nucleoside prodrugs; which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these nucleoside analog prodrugs, acyclovir prodrugs, analogs of valacyclovir, nucleoside analogs and nucleoside prodrugs meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-17 provide for the use of a nucleoside analog or a prodrug thereof or a nucleoside analog prodrug, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

One interpretation of instant claims 12-17 is "method of use" claims. In order to advance prosecution in this case, 12-17 will be interpreted as "**method of use**" claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostetler U.S. Patent No. 5,654,286 A in view of Shinkai et al. Bioorgan & Med. Chem. 1996 (U).

Hostetler teaches nucleosides, such as acyclovir and ganciclovir for topical treatment of psoriasis (column 2, lines 56-65). Doses are administered in the range of about 0.01 gm% to 10 gm % administered one to six times daily topically (column 10,

line 65 to column 11, line 5). It does not teach administration of valacyclovir and it does not teach administration by mouth (orally).

It is *prima facie* obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. The respective functions of acyclovir and valacyclovir are well known. One of ordinary skill in the art could have substituted acyclovir for valacyclovir and the results of the substitution would have been predictable motivated by the teaching of Shinkai et al. (U) that valacyclovir is the L-valyl ester prodrug of acyclovir and exhibits similar potency but has more favorable pharmacokinetic characteristics, requiring less frequent dosing schedule and achieving higher blood plasma levels than acyclovir (see summary).

It would have been *prima facie* obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

The prior art showed that administration of acyclovir for psoriasis. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the nucleoside analog, valacyclovir taught in Shinkai et al. for the acyclovir of Hostetler for the predictable result of more favorable pharmacokinetic characteristics, requiring less frequent dosing schedule and achieving higher blood plasma levels.

Regarding instant claims 18-20, drawn to the article of manufacture comprising packaging material and a pharmaceutical composition comprising an amount of nucleoside analog prodrug, such as valacyclovir, the nucleoside analog prodrug, valacyclovir, is well-known from the teaching of Shinkai et al. Regarding the kit, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. The packaging material and/or label of the instant claims are not given patentable weight to the composition absent a new and unobvious functional relationship between the printed matter and the substrate. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035; In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad U.S. Patent No. 6,296,880 B1 in view of Shinkai et al. Bioorgan & Med. Chem. 1996 (U).

Murad teach treatment of psoriasis (see abstract, column 3, lines 9-15, column 4, lines 22-23 and line 62, column 5, line 3 and line 21) with antimicrobial's such as acyclovir (column 4, line 11, column 6, line 64). Route of administration may be oral or topical (column 9, lines 49-62 and column 10, lines 60-67). Doses of the active agent are from about 1mg to 2000 mg (2 grams) which partially overlaps and encompasses the claimed doses of between 1 gram and 3 grams per day.

It does not teach administration of valacyclovir.

It is *prima facie* obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. The respective functions of acyclovir and valacyclovir are well known. One of ordinary skill in the art could have substituted acyclovir for valacyclovir and the results of the substitution would have been predictable motivated by the teaching of Shinkai et al. (U) that valacyclovir is the L-valyl ester prodrug of acyclovir and exhibits similar potency but has more favorable pharmacokinetic characteristics, requiring less frequent dosing schedule and achieving higher blood plasma levels than acyclovir (see summary).

It would have been prima facie obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

The prior art showed that administration of acyclovir to psoriasis. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the nucleoside analog, valacyclovir taught in Shinkai et al. for the acyclovir of Hostetler for the predictable result of more favorable pharmacokinetic characteristics, requiring less frequent dosing schedule and achieving higher blood plasma levels

Regarding instant claims 18-20, drawn to the article of manufacture comprising packaging material and a pharmaceutical composition comprising an amount of

nucleoside analog prodrug, such as valacyclovir, the nucleoside analog prodrug, valacyclovir, is well-known from the teaching of Shinkai et al. Regarding the kit, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. The packaging material and/or label of the instant claims are not given patentable weight to the composition absent a new and unobvious functional relationship between the printed matter and the substrate. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035; In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

September 28, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614